

## TITLE

Rotatable Catheter Assembly

## CROSS-REFERENCE TO RELATED APPLICATIONS

5 Not Applicable

## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

## 10 BACKGROUND OF THE INVENTION

Description of the Related Art

Stent delivery systems for deployment of one or more stent bodies at or around a vessel bifurcation have been proposed. Often such stents generally have an opening which allows for unimpeded blood flow into one or more side branch arteries, and/or through which an additional stent body may be deployed. However, problems are still encountered in orienting a stent relative to the side branch at the bifurcation of the primary and secondary passages. Moreover, such bifurcated assemblies are typically specially manufactured at an increased cost over a more standard stent intended for single vessel deployment.

20 In delivering a stent to a vessel location, many current devices rely on either passive torque (e.g., pushing the stent forward and allowing the stent that is fixed on the guidewire/balloon to passively rotate itself into place) or creating torque from outside of the patient to properly orient the medical device in the passage. Such catheter assemblies include those described in U.S. 5,749,825; U.S.6,599,315 and U.S.6,290,673  
25 the entire content of each of which being incorporated herein by reference.

Unfortunately such devices still often require a significant portion of the catheter assembly in addition to the balloon to be subjected to torque in order to align the stent with the side branch opening of the bifurcation. Subjecting the catheter as well as a vessel to such extraneous torque may be considered undesirable.

30 Thus, a need exists to provide a catheter which is capable of allowing a

medical device such as a stent to be easily maneuvered and aligned at a vessel bifurcation or other location without the need to torque or rotate the entire catheter shaft in order to align the stent at a vessel bifurcation. Various devices and methods described herein address this need by providing a catheter system with a rotatable  
5 balloon about which a stent may be mounted on or engaged to. The rotatable balloon is independently rotatable relative to the inner and/or outer catheter shafts thereby eliminating the need to apply torque to the catheter shaft to align the stent at a vessel bifurcation.

All US patents and applications and all other published documents  
10 mentioned anywhere in this application are incorporated herein by reference in their entirety.

Without limiting the scope of the invention a brief summary of some of the claimed embodiments of the invention is set forth below. Additional details of the summarized embodiments of the invention and/or additional embodiments of the invention  
15 may be found in the Detailed Description of the Invention below.

A brief abstract of the technical disclosure in the specification is provided as well only for the purposes of complying with 37 C.F.R. 1.72. The abstract is not intended to be used for interpreting the scope of the claims.

## 20 BRIEF SUMMARY OF THE INVENTION

As used herein the term 'stent' refers to an expandable prosthesis for implantation into a body lumen or vessel and includes devices such as stents, grafts, stent-grafts, vena cava filters, etc. In some embodiments a stent may be at least partially constructed of any of a variety of materials such as stainless steel, nickel, titanium, nitinol,  
25 platinum, gold, chrome, cobalt, as well as any other metals and their combinations or alloys. A stent may be at least partially constructed of a polymer material. A stent may be at least partially constructed of a shape-memory polymer or material. A stent may be balloon expandable, self-expandable, hybrid expandable or a combination thereof. In some embodiments a stent may include one or more areas, bands, coatings, members etc that is  
30 (are) detectable by imaging modalities such as X-Ray, MRI or ultrasound. In some

embodiments at least a portion of the stent is at least partially radiopaque. In some embodiments a stent may include one or more therapeutic and/or lubricious coatings applied thereto.

Some embodiments of the present invention are directed to catheter systems  
5 wherein the catheter comprises balloon which is independently rotatable about the catheter shaft or shafts. For example, in at least one embodiment the invention is directed to a catheter having an inner shaft wherein a distal waist of the balloon is rotatably engaged and an outer shaft wherein a proximal waist of the balloon is rotatably engaged. In some  
10 embodiments the catheter comprises only a single catheter shaft about which the balloon is rotatably engaged.

In at least one embodiment each balloon waist is disposed about a collar, the collar may be fixedly engaged to a portion of the catheter shaft or may be selectively rotatable there about. In at least one embodiment a first portion of a catheter shaft has a collar engaged there to, the collar may be fixed or rotatable thereabout. Where the collar is  
15 fixed a rotatable balloon is disposed about the catheter shaft in a manner such that each waist of the rotatable balloon is rotatably disposed about a collar. Where the collars are rotatable about the catheter shaft, each waist of the balloon is fixedly disposed to the outer surface of a collar so that the balloon is made rotatable about the catheter shaft as a result.

The collars are at least partially constructed of an electro-active polymer  
20 (EAP) which expands to a predetermined extent upon exposure to an electric current. In some embodiments the collars are exposed to the electric current by a conductive element. A second conductive element is provided by exposing the fluid that inflates the balloon, which is typically saline and/or a radiopaque solution) to a similar electrical current. In some embodiments the EAP material of the collar and/or the collar itself will expand about  
25 0.5 % to about 20% expansion in a predetermined manner and/or direction when subjected to an electric current of 0.001 microAmps to 1 milliAmps (-2 to +2 V). In at least one embodiment a collar is constructed of one or more conductive elements such as gold, silver, platinum, etc., which is at least partially surrounded by a layer of EAP material.

In embodiments where the collars are rotatable about the catheter shaft, prior  
30 to exposure to the electric current the collars define an inside diameter which is sufficiently

greater than the outer diameter of the catheter shaft to which they are respectively engaged so as to allow the collars, and thus the balloon mounted thereto, to freely rotate about the catheter shaft(s). When the collars are exposed to the electric current through one or more conductive members within and/or adjacent to the catheter the collars will expand and thus  
5 effectively contract around the respective catheter shaft to which they are engaged, effectively sealing the interior of the balloon which may then be expanded.

In embodiments where the collars are fixed to the catheter shaft, prior to exposure to the electric current the collars define an outside diameter which is sufficiently less than the inner diameter of the catheter waists which are respectively disposed there  
10 about so as to allow the waists, and thus the balloon body extending there between, to freely rotate about the collars. When the collars are exposed to the electric current through one or more conductive members within and/or adjacent to the catheter the collars will expand and thus effectively push against the respective catheter waists, effectively sealing the interior of the balloon which may then be expanded.

15 In order to get an electric current to a collar, in some embodiments a conductive wire or member of gold, gold plated SS, Nitinol, silver coated SS, Elgiloy, etc. extends from a current source to a collar through or adjacent to the catheter shaft. In some embodiments the conductive member is in the form of an insulated wire or other member which engages the collar via an exposed end which extends through an opening in the  
20 catheter shaft. Such a member may be co-extruded with one or more catheter shafts and/or balloon. A proximal end of the wire is engaged to a current source which may be activated to transmit the current through the wire to the collar when desired. In at least one embodiment a conductive member is at least partially contained within one or more lumens defined by the catheter.

25 In some embodiments a collar is bonded, welded, adhesively engaged, mechanically engaged or otherwise fixed to a balloon waist. In some embodiments a collar is bonded, welded, adhesively engaged, mechanically engaged or otherwise engaged to a portion of the catheters shaft underlying a waist of the balloon which is rotatable thereabout. In some embodiments, where the collar is fixed to a balloon waist the waist  
30 may be reinforced with one or more layers of transition material positioned between the

collar and the balloon waist in order to facilitate engagement there between. In some embodiments the waist may likewise be reinforced. In some embodiments a transition material includes but is not limited to: Plexar, Sellar, EMS Hytrel, and other similar materials. In at least one embodiment the collar is integral with the balloon waist. In at least one embodiment the collar is integral with the catheter shaft. In at least one embodiment a collar comprises only EAP material.

In some embodiments the catheter comprises one or more support members or rings which support the region of the catheter shaft(s) about which the collars are mounted. A support ring may be constructed of one or more materials including but not limited to: Polyamide, Nylon, Pebax, Acetyl, PTFE, HDPE, PI, PET, Christamid, Vestimid, metal reinforced polymers, braided reinforced polymers, Stainless steel, Nitinol, etc.

In some embodiments the catheter is disposed about a primary guidewire. In at least one embodiment the catheter is a fixed wire catheter. In some embodiments a secondary guidewire housing through which a side branch or secondary guidewire is positioned. In some embodiments the secondary guidewire housing is engaged to the balloon. In at least one embodiment the secondary guidewire housing is positioned at least partially under the stent prior to delivery.

In some embodiments the secondary guidewire extends into a side branch of a bifurcation through a secondary opening of the stent. By advancing the catheter along the secondary guidewire as the catheter is advanced through the main vessel to the bifurcation rotation will be imparted to the balloon to orient the secondary opening of the stent and/or the secondary guidewire housing with the side branch of the vessel bifurcation. When properly oriented the collars are subjected to an electric current thereby imparting the balloon with a fluid seal sufficient to allow inflation of the balloon.

These and other embodiments which characterize the invention are pointed out with particularity in the claims annexed hereto and forming a part hereof. However, for a better understanding of the invention, its advantages and objectives obtained by its use, reference should be made to the drawings which form a further part hereof and the accompanying descriptive matter, in which there is illustrated and described a embodiments of the invention.

## BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

A detailed description of the invention is hereafter described with specific reference being made to the drawings.

5               FIG. 1 is a perspective view of an embodiment of the invention comprising a catheter assembly having a rotatable balloon.

FIG. 2 is a longitudinal cross-sectional view of an embodiment of the invention being advanced to a vessel bifurcation and prior to balloon expansion.

10              FIG. 3 is a longitudinal cross-sectional view of the embodiment shown in FIG. 2 shown during expansion of the balloon.

FIG. 4 is a longitudinal cross-sectional view of an embodiment of the invention being advanced to a vessel bifurcation and prior to balloon expansion.

FIG. 5 is a longitudinal cross-sectional view of the embodiment shown in FIG. 4 shown during expansion of the balloon.

15              FIG. 6 is a block diagram illustrating the conductive relationship of the catheter assembly shown in FIG. 1 with a source of electric current.

FIG. 7 is a longitudinal cross-sectional view of an embodiment of the invention.

20              FIG. 8 is an enlarged partial side view of a collar such as may be utilized by the embodiment shown in FIG. 1 shown prior to exposure to an electric current.

FIG. 9 is an enlarged partial side view of the collar illustrated in FIG. 8 shown during exposure to an electric current.

FIG. 10 is a partial side view of the balloon shown in FIG. 1 with a stent and guidewire housing shown engaged thereto.

25              FIG. 11 is a close up view of a secondary opening of a region of the assembly shown in FIG. 1.

FIG. 12 is a cross sectional view of the balloon shown in FIG. 10.

FIG. 13 is a longitudinal cross-sectional view of the stent depicted in FIGS. 10-12 shown after delivery and withdrawal of the catheter assembly.

30              FIG. 14 is a longitudinal cross-sectional view of an embodiment of the

invention wherein the catheter assembly comprises a single catheter shaft.

FIG. 15 is a longitudinal cross-sectional view of an embodiment of the invention wherein the balloon wall comprises a conductive member is conductive communication with the proximal and distal collars.

5               FIG. 16 is a partial view of a catheter assembly showing an optional engagement configuration between the balloon waist and the collar.

FIG. 17 is a partial view of a catheter assembly showing an optional engagement configuration between the balloon waist and the collar.

10             FIG. 18 is a partial view of a catheter assembly showing an optional engagement configuration between the balloon waist and the collar.

FIG. 19 is a partial view of a catheter assembly showing an optional engagement configuration between the catheter shaft and the collar.

#### DETAILED DESCRIPTION OF THE INVENTION

15             While this invention may be embodied in many different forms, there are described in detail herein specific embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

20             For the purposes of this disclosure, like reference numerals in the figures shall refer to like features unless otherwise indicated.

Referring now to the drawings which are for the purposes of illustrating embodiments of the invention only and not for purposes of limiting same, in at least one embodiment of the invention, an example of which is shown in FIG. 1, a catheter assembly 10 comprises an inner catheter shaft 12, an outer catheter shaft 14 and a rotatable balloon 16 25 rotatably engaged to one or both shafts 12 and 14.

Balloon 16 may be a typical angioplasty, stent delivery balloon or other inflatable member which may be used or incorporated into a catheter assembly. Typically the wall thickness of the waists 20 and 22 of the balloon 16 will be thicker than the thickness of the balloon body which extends there between. In some cases the thickness of one or both waists is 30 about twice that of the balloon body but may be about 10 times more resistant to radial

pressures.

In order to allow the balloon 16 to rotate freely relative to the shaft or shafts 12 and 14 each waist 20 and 22 of the balloon 16 is engaged to a collar 30 and 32 respectively. Collars 30 and 32 are at least partially constructed of EAP material such including of Poly-  
5 pyrrole (PPY), Poly-Aniline (PAni), Poly-Thiophene (PTH), Poly-Paraphenylene Vinylene (PPV), Nafion, Bucky paper or any other ionic electro-active polymer that is considered to have low voltage, low speed, high stress (up to 500 MPa), characteristics. EAP materials have the unique characteristic of expanding in size when exposed to an electric current of predetermined current or voltage. For example, in some embodiments the EAP material of  
10 the collar and/or the collar itself will expand about 0.5 % to about 20% when exposed to an electric current of 0.001 microAmps to 1 milliAmps (-2 to +2 V).

EAP materials and some of their notable characteristics are described in an article entitled *Electro-Active Polymer Actuators for Planetary Applications* by Y. Bar-Cohen et al. and published in Paper No. 3669-05 of the Proceedings of SPIE Annual  
15 International Symposium on Smart Structures and Materials, March 1999, Newport Beach, CA. SPIE Copyright 1999, the entire contents of which being incorporated herein by reference.

As a result of EAP materials unique expansion characteristics a collar comprising EAP material such as collars 30 and 32 may be formed to have a pre-current  
20 shape and a post-current shape that is different or larger than the pre-current shape.

Pre-current refers to the condition of the collars 30 and 32 before the collars are exposed to an electric current sufficient to activate the EAP material. Post-current refers to the condition of the collars 30 and 32 when the collars are being exposed to an electric current sufficient to activate the expansion of the EAP material.

25 In some embodiments the collars 30 and 32 in the pre-current state, are constructed to rotate freely about the respective catheter shafts 12 and 14 and to become fixed in position and engagement to the respective catheter shafts 12 and 14 in the post current state. In such embodiments, an example of which is shown in FIGs. 2 collars 30 and 32 are provided with a pre-current inner diameter, which is sufficiently greater than the  
30 outer diameter of the shafts 12 and 14 to allow the collar, and thus the balloon 16 engaged



thereto, to freely rotate about the shafts 12 and 14 before exposure to the electric current.

When the collars 30 and 32 are exposed to an electric current, illustrated by arrows 62, the expansion of the EAP material causes the inner diameter of the collars to expand such as is shown in FIG. 3. As a result, each collar 30 and 32 will contract around their respective catheter shafts 12 and 14 effectively sealing the collars 30 and 32 thereto. As a consequence of the collars 30 and 32 being sealed against the shafts 12 and 14, the interior 40 of the balloon 16 is made effectively fluid tight against the shafts thereby allowing the balloon to be expanded such as by inflation via an inflation fluid through inflation lumen 42.

In some embodiments, an example of which is shown in FIG. 4, the collars 30 and 32 are fixedly engaged about shafts 12 and 14 respectively. In the pre-current state, the balloon 16 is rotatably disposed about the collars 30 and 32 such that the distal waist 20 of the balloon 16 is rotatably disposed about the distal collar 30 and the proximal waist 22 of the balloon 16 is rotatably disposed about the proximal collar 32 of the balloon 16. In the pre-current state each collar 30 and 32 has an outer diameter less than the inner diameter defined by the respective balloon waists 20 and 22. In the post-current state the collars 30 and 32 expand outward to engaged the waists 20 and 22 such as in the manner shown in FIG. 5. By engaging the waists 20 and 22 in this manner the interior 40 of the balloon 16 is made effectively fluid tight against the collars 30 and 32 thereby allowing the balloon to be expanded such as by inflation via an inflation fluid through inflation lumen 42.

In some embodiments, such as in the example shown in FIGs. 2-5, it may be beneficial to support the distal end of the outer shaft 14 with a support ring or member 17. The support ring may be disposed about the inner shaft 12 and/or may be merely internally engaged to the outer shaft 14. In some embodiments the ring 17 extends between the inner shaft 12 and the outer shaft 14 but defines one or more openings there through which further define the inflation lumen 42. Ring 17 may be constructed of one or more materials including but not limited to: stainless steel coil, stainless steel stent like structure, stainless steel spiral cut hypotube, Nitinol, acetyl, PI, HDPE, LX2/TR55, Nanocomposites, Ceramics. In some embodiments the length of the ring 17 will be approximately the same length as the collar 32 and/or 30 which it supports.

In some embodiments the inner shaft 12 has one or more bands 56 of radiopaque material. In some embodiments a band(s) 56 is detectable by imaging modalities such as X-Ray, MRI or ultrasound.

As shown in FIGs. 2-5, one or more conductive wires or other members 50  
5 may extend from a proximal region of the catheter 10 to the collars 30 and 32. A current source 60 as depicted in FIG. 6 is in communication with the wire(s) 50 which when activated transmits the electric current, illustrated by arrows 62 in FIG. 2-5, to the wires 50 and collars 30 and 32, thereby causing expansion of the EAP material in the collars to sealingly engage the balloon 16 to the shafts 12 and 14. The circuit which the current  
10 traverses through the members 50 and collars 30 and 32 may be completed as a result of the conductive nature of the saline or other fluid 300 which is used to expand the balloon 16. In some cases the conductive nature of some bodily fluids may also be utilized to complete the circuit.

Wires 50 maybe co-extruded with the material of either or both catheter  
15 shafts 12 and 14. An opening 15 in the shaft(s) exposes the wire 50 to the collars 30 and 32 in the manner shown in FIGs. 2-5. Alternatively, the catheter assembly 10 may define any number of lumens through which a wire or wires may be positioned. In some embodiments a wire 50 may extend at least partially through the inflation lumen 42 to one or both collars 30 and 32.

20 As indicated above the collars 30 and 32 are at least partially constructed of one or more EAP materials. However, in order to more effectively transmit the electric current to the EAP material in some embodiments, such as shown in FIGs. 2-5, the collars 30 and 32 include a conductive member or marker 34 about which at least one layer 36 of EAP material is engaged. The markers 34 may be any type of conductive material or  
25 materials and is preferably biocompatible. Appropriate materials for the construction of the markers 34 include but are not limited to, gold, platinum, nitinol, silver, etc. The layer 36 of EAP material may partially or entirely surround the marker 34.

In the embodiment depicted in FIGs. 2-5, the collars 30 and 32 are constructed so that at least a portion of the inside surface of the collar is defined by a  
30 marker 34. This allows direct contact of the conductive material of the marker to be

directly engaged to the conductive wire 50. In this manner the current received by the marker may be distributed to the surrounding layer of EAP material in a substantially uniform manner to allow the EAP material engaged thereto to expand in a substantially uniform manner.

5 As illustrated in FIG. 1 the catheter may be equipped with one or more hubs, tips rings or other devices 90 and/or 92 which may abut the collars 30 and/or 32 to limit the potential for undesired longitudinal migration of the balloon 16 relative to the catheter shafts 12 and 14. In the embodiment shown in FIG. 7, the outer shaft 14 is provided with a necked region 91 wherein the outer and/or inner diameter of the shaft 14 narrows adjacent  
10 to the proximal collar 32. The reduced diameter necked region 91 may include a step or shoulder 93 which may abut the proximal collar 32 and/or proximal waist 22 thereby preventing longitudinal migration of the balloon 16 in the proximal direction.

As is also shown in FIG. 7, in some embodiments the distal hub may be in the form of the catheter tip 92 which distally abuts the proximal collar 30 and/or proximal  
15 waist 20 thereby preventing longitudinal migration of the balloon 16 in the distal direction.

In some embodiments where the collars 30 and 32 are rotatable about the catheter shaft in the pre-current state, in some cases the collars 30 and 32 may avoid the need for hubs by rotatably disposing the collars 30 and/or 32 to a conductive ring 52 such as in the manner depicted in FIGs. 8 and 9. In the embodiment shown in FIGs. 8 and 9 the  
20 conductive wire 50 may further comprise a conductive ring 52 which projects radially outward from the catheter shaft 12/14. The EAP layer 36 and/or the marker 34 of a collar 30/32 may define a groove or track 38 which is rotatably engaged to the ring 52 prior to exposure of the collar to the electric current. When current 62 is supplied to the ring 52, and thus the collar 30/32 as well, the layer 36 of EAP material will expand to close the  
25 groove against the ring 52 and seal the collar 30/32 about the shaft 12/14.

In the various embodiments shown in FIGs. 2-5, prior to electric activation of the collars 30 and 32, the balloon 16 is freely rotatable about the catheter shafts 12 and 14. This capacity to freely rotate allows a stent 70 mounted on the balloon 16 to be rotationally oriented within a body vessel 100 during advancement of the assembly  
30 without necessitating torquing of the catheter shafts 12 and/or 14. Because the balloon 16

is freely rotatable, it is desirable to provide the balloon 16 with a mechanism which allows the balloon 16 to be rotated to a desired position.

In the various embodiments described herein the catheter assembly 10 may be a fixed wire catheter or any other catheter design. In the embodiment depicted in FIGs. 1-5 for example the catheter is an over the wire design wherein the inner shaft 12 defines a primary guidewire lumen 11 along which a primary guidewire 13 may be advanced.

In some embodiments, such as are illustrated in FIGs. 1-5, such a mechanism is comprised of a secondary guidewire housing 80. Housing 80 may be comprised of an tubular member which defines a secondary guidewire lumen 84 through which a secondary guidewire 86 may be advanced. The housing 80 is engaged to the balloon 16 or defined by the balloon wall as desired. The housing 80 may be comprised of one or more tubular members 82. Where multiple members 82 are included in the housing 80, the members are disposed about one another to provide the housing with a variety of flexibility, hardness, and/or stiffness characteristics as desired. As such the housing 80 may be constructed of any of a wide variety of materials including metal(s), polymer(s), natural rubber, silicone, multilayer materials, urethanes, Pebax, HDPE, etc.

When the stent 70 is properly positioned on the balloon 16, such as in the manner depicted in FIGs. 1-5, a proximal portion 72 of the stent 70 is also disposed about at least a portion of the secondary guidewire housing 80. When the stent 70 is thusly positioned about the balloon 16 and the housing 80, in some embodiments, such as for example that shown in FIGs. 10 and 11, at least a portion of the housing 80 and/or the secondary guidewire 86 extends distally through a cell opening 76 of the stent 70.

Stent 70 may be a stent, such as is shown in FIG. 10, which is at least partially constructed of a plurality of interconnected struts, connectors or members 75. The stent 70 defines a proximal opening 71, a distal opening 73 and a flow path 77 there between. The cell openings 76 are in fluid communication with the flow path 77.

When the secondary guidewire 86 and/or the secondary guidewire housing 80 is threaded through one of the cell openings 76 when the stent is positioned onto the assembly 10, such as is shown in FIG. 1, and 10-12, the members 75 that define the selected cell opening 78, as well as the shape of the opening 78 through which the secondary guidewire 86 exits the stent,

may be distorted or modified in order to accommodate the passage of secondary guidewire 86 and/or the secondary guidewire housing 80 there through.

This modified cell opening 78, hereinafter referred to as secondary opening 78, is positioned on the stent 70 between the proximal opening 71 and the distal opening 73. The manner in which the secondary opening 78, the members 75 adjacent thereto, and to an extent the stent 70 itself, are modified or distorted by the position of the secondary guidewire and/or secondary guidewire housing is best illustrated in FIGs. 10 and 12.

It should be noted that when the stent 70 is placed on the balloon 16 in the manner described above, the distortion of the secondary opening 78 and the adjacent members 75 may be of a minimal nature providing only a sufficient alteration to the cell to allow sliding passage of the secondary guidewire 86, and if desired a distal portion of the secondary guidewire housing 80 there through. As such, the actual size of the secondary opening 78 may be substantially similar, or only marginally different than that of the surrounding cell openings 76.

It should also be further noted that while stent 70 may be a standard "single vessel" stent that is provided with a secondary opening 78 in the manner described above, the stent 70 may also be a bifurcated stent having a trunk and/or stem portion, with one or more leg portions and/or branch openings adjacent thereto, through which the secondary guidewire may be passed. Such bifurcated stents and stent assemblies are well known in the art.

In some embodiments, the secondary guidewire 86 is merely slid between the balloon 16 and the stent 70 without the use of a housing 80. In some embodiments, where the stent 70 is to be positioned substantially proximal to a side branch of the bifurcation, the guidewire 86 and/or housing 80 may be configured to extend under the entire length of the stent 70.

In operation, the secondary guidewire 86 is initially advanced through the vessel 100 and into a side branch 102 of a bifurcation 104. By advancing the catheter assembly 10 along the secondary guidewire 86 in the manner described above, the balloon 16 and the stent 70 disposed thereabout will be rotated to align the secondary opening 78 of the stent 70 with the side branch vessel 102. Once properly positioned in this manner the collars 30 and 32 may be activated and the balloon 16 expanded to deliver the stent 70 such as in the manner depicted in FIGs. 3 and 5. As shown in FIG. 13, once the stent 70 is

delivered the balloon is deflated and the assembly is withdrawn from the vessel 100.

In some cases, the stent 70, or one or more portions of the assembly 10 thereof, may be configured to deliver one or more therapeutic agents to a delivery site within the vessel 100 or one or more areas adjacent thereto such as shown in FIGs. 2-5.

5 To better accommodate placement of a therapeutic agent on the stent 70, in some instances one or more stent members 75, such as is shown in FIG. 10, maybe configured to include one or more holes, notches, or other surface features to which one or more therapeutic agents 200 may be placed for delivery to the aneurysm site. A therapeutic agent may be placed on the stent in the form of a coating. Often the coating includes at least one  
10 therapeutic agent and at least one polymer.

A therapeutic agent may be a drug, a non-genetic agent, a genetic agent, etc. Some examples of suitable non-genetic therapeutic agents include but are not limited to: anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as  
15 enoxaprin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine; antineoplastic/antiproliferative/anti-miotic agents such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and  
20 thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine and ropivacaine; anti-coagulants such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet peptides; vascular cell growth promoters such as  
25 growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters, vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin; bifunctional  
30 molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents;

vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms, and any combinations thereof.

Where an agent includes a genetic therapeutic agent, such a genetic agent may include but is not limited to: anti-sense DNA and RNA; DNA coding for anti-sense RNA, tRNA or rRNA to replace defective or deficient endogenous molecules; angiogenic factors including growth factors such as acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor  $\alpha$  and  $\beta$ , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor  $\alpha$ , hepatocyte growth factor and insulin like growth factor; cell cycle inhibitors including CD inhibitors, thymidine kinase ("TK") and other agents useful for interfering with cell proliferation; at least one of the family of bone morphogenic proteins ("BMP's") such as BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7; dimeric proteins such as homodimers, heterodimers, or combinations thereof, alone or together with other molecules; molecules capable of inducing an upstream or downstream effect of a BMP such as "hedgehog" proteins, or the DNA's encoding them and any combinations thereof.

Where a therapeutic includes cellular material, the cellular material may include but is not limited to: cells of human origin (autologous or allogeneic); cells of non-human origin (xenogeneic) and any combination thereof. Some examples of cellular material include but are not limited to the following:

SP – (side population cells) These cells are thought to be some of the most primitive adult stem cells. They are isolated by a specific FACS technique utilizing the ability of SP cells to exclude Hoechst dye from the nucleus. In addition to bone marrow, SP cells have been isolated from most tissues, including: cardiac and skeletal muscle. By the more common surface protein identification these cells are  $\text{Lin}^-$ ,  $\text{Sca-1}^+$ ,  $\text{c-Kit}^+$ ,  $\text{CD43}^+$ ,  $\text{CD45}^+$ ,  $\text{CD34}^-$

Lin<sup>-</sup> - (lineage negative cells) This group of cells is isolated from the bone marrow and all cells which have differentiated to a specific lineage (e.g. red blood cells) have been

removed. Therefore leaving all of the stem and progenitor cells. This is beneficial because all primitive cells remain, but may reduce efficiency by including irrelevant, primitive cell types.

- 5 Lin<sup>-</sup>CD34<sup>-</sup> - Although CD34<sup>+</sup> cells have received much attention, many articles have been published lately which suggest the most primitive bone marrow derived stem cells are CD34<sup>-</sup>

Lin<sup>-</sup>CD34<sup>+</sup> - Presence of the cell surface protein CD34 has been used to identify hematopoietic stem cells. However, the marker is also present on progenitor cells and white blood cells of various levels of maturity.

- 10 Lin<sup>-</sup>cKit<sup>+</sup> - cKit is the cell surface receptor for stem cell factor, and therefore a logical choice for stem cell selection. Most widely studied from bone marrow sources, but have also been isolated from the heart.

- MSC – (mesenchymal stem cells) Named so because ordinarily these cells differentiate into cells of mesenchymal tissues (e.g. bone, cartilage, fat), but may also differentiate into  
15 cardiomyocytes under certain conditions. Easily isolated from bone marrow and, unlike hematopoietic stem cells, proliferate in vitro. A subpopulation of MSCs has been shown to self-renew faster and have a greater potential for multipotential differentiation than the general MSC population. D. Prockop from Tulane U. is publishing in this area.

- 20 Cord Blood Cells – Derived from the blood remaining in the umbilical vein following child birth. This blood has been shown to contain a higher percentage of immature stem cells or progenitor cells. Typically, a matched donor must be found for patients, but a lower incidence of graft versus host disease compared to stem cell isolation from adult blood has been reported. Disadvantages include: insufficient cell number in small  
25 blood volumes, unforeseen congenital defects, and contamination by mother's blood which is likely not HLA matched.

- Cardiac or other tissue derived stem cells – Most work to date has focused on isolating stem cells from bone marrow. This is due to extensive work in improving bone marrow transplants for chemotherapy and leukemia treatments. However, there is evidence that  
30 similar stem cells which can be identified by similar means (e.g. SP, cKit) can be



isolated from other tissues (e.g. fat, cardiac muscle).

Whole bone marrow – An “it’s in there” approach where whole bone marrow (filtered for bone particles) is transplanted. Benefits include: little processing, all stem and progenitor cells are present, and matrix proteins and growth factors may also be present. Downside – if one or two stem cell types are responsible for cardiac improvement they will only be present in very low numbers.

BM-MNCs – (bone marrow mononuclear cells) Separated from whole bone marrow by a density gradient centrifugation procedure, this population contains non-granular white blood cells, progenitor cells, and stem cells.

10 EPCs – (endothelial progenitor cells) Isolated from bone marrow based on cell surface markers, these cells will become endothelial cells. In theory, these cells will form new blood vessels when delivered to ischemic tissue.

15 Skeletal myoblasts – (or satellite cells) These cells are responsible for the regeneration of skeletal muscle following injury. They have the ability to fuse with other myoblasts or damaged muscle fibers. Cardiac muscle therapies assume these cells can integrate into the host tissue and improve tissue properties or functionally participate in contraction.

20 MDCs – (muscle derived cells) A population of cells isolated from adult skeletal muscle which are similar to myoblasts. The isolation technique preplating entails collecting cells which attach to culture dishes at different times after biopsy. Cells with the best potential plate in the 6<sup>th</sup> group and takes several days to obtain. Investigators working with these cells claim they are a refined population of myoblasts and should result in higher engraftment efficiencies and efficacious procedures.

25 Go cells – Recently isolated from adult skeletal muscle, these non-satellite cells express GATA-4 and, under certain in vitro growth conditions, progress to spontaneously beating cardiomyocyte-like cells.

Endothelial cells – Transplantation of autologous endothelial cells along with a fibrin matrix induced angiogenesis and improved cardiac function in an ischemic sheep model.

Adult cardiomyocytes

30 Fibroblasts – Easily obtained from adult tissues, fibroblasts may provide growth factors or

participate in the wound healing response. Fibroblasts play a critical role in wound healing; the synthesis and deposition of extracellular matrix. Fibroblasts commonly become contractile in wound healing environments.

Smooth muscle cells – Isolated from arteries, these cells may participate or encourage angiogenesis and/or beneficial cardiac remodeling following MI.

MSCs + 5-aza – Culture of mesenchymal stem cells with 5-aza forces differentiation into cardiomyocytes. These cells beat spontaneously after treatment.

Adult cardiac fibroblasts + 5-aza – In theory, in vitro treatment of cardiac fibroblasts with 5-aza will result in differentiation into myogenic cells.

10 Genetically modified cells – Isolation of cells from the patient and genetically modifying them in vitro to encourage production of proteins or differentiation into a cell type which will be beneficial for treating heart failure.

Tissue engineered grafts – Isolation of cells from the patient which are then seeded onto and cultured within resorbable scaffolds (e.g. collagen, PLGA). These cell seeded  
15 constructs are then implanted into the patient.

MyoD scar fibroblasts – MyoD family of transcription factors prompt skeletal muscle cell differentiation in fibroblasts. Procedure involves isolation of cardiac scar fibroblasts, genetic transfection with MyoD in vitro and delivery of the cells to the heart to encourage myogenesis.

20 Pacing cells – Genetically modified fibroblasts which become electrically conducting and signal generators.

Embryonic stem cell clones – Use of cloning technology to produce cardiomyocytes, progenitors, or stem cells which are genetically identical to the patient.

Embryonic stem cells – These cells are the most primitive of cells and will differentiate into  
25 functional cardiomyocytes under certain conditions. Both political and technological hurdles must be overcome before commercialization of this technology.

Fetal or neonatal cells – Isolated from the heart of donors, these cells may incorporate into host tissue without immune rejection. Some cardiomyocyte progenitor cells must be present due to the continued growth of the heart in fetal and neonatal humans.

Immunologically masked cells – Allogeneic cell sources (e.g. donor cardiomyocytes) are currently unfeasible due to immune rejection. However, masking technologies have been developed which could make this technology feasible.

5 Tissue engineered grafts – Isolation of cells from a donor which are then seeded onto and cultured within resorbable scaffolds (e.g. collagen, PLGA). These cell seeded constructs are then implanted into the host or recipient.

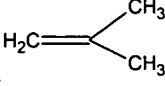
Genetically modified cells – Isolation of cells from a donor and genetically modifying them in vitro to encourage production of proteins or differentiation into a cell type which will be beneficial for treating heart failure. The modified cells will then be  
10 transplanted into the host or patient.

Teratoma derived cells – A teratocarcinoma is a form of cancer in which the tumor is composed of a heterogeneous mixture of tissues. Through isolation of cells from this tumor and in vitro manipulation and culture a neuronal cell line has been developed. Layton Biosciences has successfully used these cells to form new brain tissue in stroke  
15 patients. Similar techniques may be used to produce a myogenic cell line.

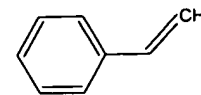
Where a therapeutic agent comprises at least one polymer agent or coating, the at least one coating may include but is not limited to: polycarboxylic acids; cellulosic polymers, including cellulose acetate and cellulose nitrate; gelatin; polyvinylpyrrolidone;  
20 cross-linked polyvinylpyrrolidone; polyanhydrides including maleic anhydride polymers; polyamides; polyvinyl alcohols; copolymers of vinyl monomers such as EVA; polyvinyl ethers; polyvinyl aromatics; polyethylene oxides; glycosaminoglycans; polysaccharides; polyesters including polyethylene terephthalate; polyacrylamides; polyethers; polyether sulfone; polycarbonate; polyalkylenes including polypropylene, polyethylene and high  
25 molecular weight polyethylene; halogenated polyalkylenes including polytetrafluoroethylene; polyurethanes; polyorthoesters; proteins; polypeptides; silicones; siloxane polymers; polylactic acid; polyglycolic acid; polycaprolactone; polyhydroxybutyrate valerate and blends and copolymers thereof; coatings from polymer dispersions such as polyurethane dispersions (BAYHDROL<sup>®</sup>, etc.), fibrin, collagen and  
30 derivatives thereof; polysaccharides such as celluloses, starches, dextrans, alginates and

derivatives; hyaluronic acid; squalene emulsions; polyacrylic acid, a copolymer of polylactic acid and polycaprolactone; medical-grade biodegradable materials such as PGA-TMC, Tyrosine-Derived Polycarbonates and arylates; polycaprolactone co butyl acrylate and other co polymers; Poly-L-lactic acid blends with DL-Lactic Acid; Poly(lactic acid-co-glycolic acid); polycaprolactone co PLA; polycaprolactone co butyl acrylate and other copolymers; Tyrosine-Derived Polycarbonates and arylate; poly amino acid; polyphosphazenes; polyiminocarbonates; polydimethyltrimethylcarbonates; biodegradable CA/PO<sub>4</sub> 's; cyanoacrylate; 50/50 DLPLG; polydioxanone; polypropylene fumarate; polydepsipeptides; macromolecules such as chitosan and Hydroxylpropylmethylcellulose; surface erodible material; maleic anhydride copolymers; zinc-calcium phosphate; amorphous polyanhydrides; sugar; carbohydrate; gelatin; biodegradable polymers; and polymers dissolvable in bodily fluids; and any combinations thereof.

In some instances a suitable polymer agent or coating comprises block copolymers comprising at least one A block and at least one B block. The A blocks are preferably soft elastomeric blocks, which are based upon one or more polyolefins, or other polymer with a glass transition temperature at or below room temperature. For example, the A blocks can be polyolefinic blocks having alternating quaternary and secondary carbons of the general formulation:  $-(CRR'-CH_2)_n-$ , where R and R' are, independently, linear or branched aliphatic groups such as methyl, ethyl, propyl, isopropyl, butyl, isobutyl and so forth, or represent cyclic aliphatic groups such as cyclohexane, cyclopentane, and the like, either with or without pendant groups. Preferred polyolefinic blocks include

polymeric blocks of isobutylene, , (i.e., polymers where R and R' are methyl groups). Other examples of A blocks include silicone rubber blocks and acrylate rubber blocks.

The B blocks are preferably hard thermoplastic blocks with glass transition temperatures significantly higher than the elastomeric A blocks which, when combined with the soft A blocks, are capable of, *inter alia*, altering or adjusting the hardness of the resulting copolymer to achieve a desired combination of qualities. Examples of B blocks include polymers of methacrylates or polymers of vinyl aromatics. More specific examples



of B blocks include blocks that are (a) formed from monomers of styrene  
styrene derivatives (e.g.,  $\alpha$ -methylstyrene, ring-alkylated styrenes or ring-halogenated  
styrenes or other substituted styrenes where one or more substituents are present on the  
aromatic ring) or mixtures of the same, collectively referred to herein as “styrenic blocks”  
5 or “polystyrenic blocks” or are (b) formed from monomers of methylmethacrylate,  
ethylmethacrylate, hydroxyethyl methacrylate or mixtures of the same.

The block copolymers are provided in a variety of architectures, including  
cyclic, linear, and branched architectures. Branched architectures include star-shaped  
architectures (e.g., architectures in which three or more chains emanate from a single  
10 region), comb architectures (e.g., copolymers having a main chain and a plurality of side  
chains), and dendritic architectures (including arborescent or hyperbranched copolymers).

Some specific examples of such block copolymers include the following:  
(a) BA (linear diblock), (b) BAB or ABA (linear triblock), (c)  $B(AB)_n$  or  $A(BA)_n$  (linear  
alternating block), or (d)  $X-(AB)_n$  or  $X-(BA)_n$  (includes diblock, triblock and other radial  
15 block copolymers), where  $n$  is a positive whole number and  $X$  is a starting seed, or initiator,  
molecule. One specific group of polymers have  $X-(AB)_n$  structures, which are frequently  
referred to as diblock copolymers and triblock copolymers where  $n=1$  and  $n=2$ , respectively  
(this terminology disregards the presence of the starting seed molecule, for example,  
treating  $A-X-A$  as a single  $A$  block, with the triblock therefore denoted as  $BAB$ ). A  
20 particularly beneficial polymer from this group is polystyrene-polyisobutylene-polystyrene  
triblock copolymer (SIBS). Where  $n=3$  or more, these structures are commonly referred to  
as star-shaped block copolymers. Other examples of block polymers include branched  
block copolymers such as dendritic block copolymers, wherein at least one of the  $A$  and  $B$   
blocks is branched, for instance, where the  $A$  blocks are branched and are capped by the  $B$   
25 blocks.

In the embodiment shown in FIGS. 1-5 the assembly 10 comprises an inner  
shaft 12 and an outer shaft 14 with respective ends of the balloon 16 rotatable thereabout. It  
is noted however, that in some embodiments the catheter assembly 10 may include a single  
or inner catheter shaft 12, such as in the embodiment depicted in FIG. 14 for example,

wherein both collars 30 and 32 are disposed about the same shaft 12. Collars 30 and 32 may be rotatable or fixedly engaged to the shaft 12 in the same or similar manners as have been previously described. The balloon 16, prior to activation of the EAP material in the collars 30 and 32, is thus rotatable about the single catheter shaft 12. The shaft 12 may be  
5 molded or extruded to include an inflation lumen 42 for inflation of the balloon 16 following electrical activation of the collars 30 and 32.

It may be recognized that in order for the collars 30 and 32 to be electrically activated to trigger the expansion of the EAP material therein, an electric circuit necessarily needs to be formed between the conductive member 50, the current source 60, and each  
10 collar 30 and 32. It will be recognized however that the presence of saline (e.g. within bodily fluid such as blood, etc.) within the vessel and/or the balloon interior 40 during inflation completes the circuit to allow the current to flow to the collars as desired.

However, in some embodiments the formation of such a circuit may be a function of the assembly 10 alone. For example in the embodiment shown in FIG. 15, a  
15 first conductive wire 50a is contained within the outer shaft 14 or within the inflation lumen 42. Wire 50a extends from the current source 60 (shown in FIG. 6) to the proximal collar 32 and provides electrical communication there between. An intermediate conductive member or wire 50b extends through the wall 45 of the balloon or alternatively through the balloon interior 40 and is in communication between the collars 32 and 30. A third or  
20 interior conductive member 50c extends through the inner shaft 12 and is in communication with the distal collar 30 and extends proximally back to the current source 60 (shown in FIG. 6) to complete the circuit.

As indicated above the collars 30 and 32 may be engaged to the balloon 16, and more particularly to the respective waists 20 and 22 of the balloon 16 in a variety of  
25 manners. Some examples of such engagement are illustrated in FIGs. 16-19.

In the embodiment shown in FIG. 16 the collar 30/32 is integral with the balloon waist 20/22. In this embodiment the collar 30/32 is extruded or co-extruded with the balloon 16. In some embodiments marker 34 may likewise be co-extruded or may be subsequently secured to the structure.

In some embodiments, such as in the example shown in FIGs. 17 and 19 it may be desirable to reinforce the waist 20/22 of the balloon 16. In at least one embodiment the waist 20/22 may be supplemented with one or more layers 28 of transition material. Where the transition material 28 is external to the waist 20/22 as in the embodiment shown in FIG. 19, the layer 28 may reinforce the waist to help insure the fluid tightness of the balloon seal in the pre-current state and to improve the rotational characteristics of the balloon 16. In such an embodiment the layer 28 may be constructed of one or more strands fibers or layers of stainless steel or other suitable reinforcing material. In embodiments where the waist 20/22 is engaged to the collar 30/32 in the pre-current state, such as in FIG. 17 the transition material layer 28 may aid in bonding the material of the waist 20/22 to the material of the collar 30/32. Some examples of suitable transition materials for forming the layer 28 include but are not limited to: Plexar, Selar, EMS Hytrel, etc.

In some embodiments, such as in the example shown in FIG. 18, the use of a marker such as previously described may be unnecessary. As such a collar 30/32 of EAP may be directly welded or otherwise engaged to the waist 20/22 or in the alternative to the shaft 12/14.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1

should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim

5 listed in such dependent claim below.

With this description, those skilled in the art may recognize other equivalents to the specific embodiment described herein. Such equivalents are intended to be encompassed by the claims attached hereto.